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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/671,100	09/27/00	PINSKY	D 0575/51917-C

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EXAMINER	
DESMUX, A	
ART UNIT	**PAPER NUMBER**
1644	4

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/671,100	Pinsky et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-32 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20 , drawn to a method for treating an ischemic disorder comprising administering a Factor IXa compound, classified in class 514, subclasses 12 and 44,

II. Claims 21-24, drawn to a method for identifying a compound that is capable of improving an ischemic disorder, classified in Class 424 subclass 9.2,

III. Claims 25-28, drawn to a method for treating a reperfusion injury comprising administering a Factor IXa compound, classified in class 514, subclasses 12 and 44,

IV. Claims 29-30, drawn to a method of inhibiting clot formation comprising administering a an inactive recombinant mutein, classified in Class 514, subclass 2,

V. Claims 31-32, drawn to an assay to monitor the effect of a Factor IXa compound, classified in Class 435, subclass 4.

2. The inventions are distinct, each from the other because:

Groups I-V are unique methods. The ingredients, process steps and endpoints of Group II differ from those of Groups I/III/IV since Group II is drawn to a method for identifying a compound that is capable of improving an ischemic disorder while Groups I/III/IV are each drawn to a treatment method. The endpoint (a method of inhibiting clot formation) and the process steps (comprising administering an inactive recombinant mutein of any molecule) of Group IV differs from Groups I and III, which both have similar process steps (comprising administering a Factor IXa compound) but differ with respect to their endpoints (treating an ischemic disorder) vs (treating a reperfusion injury), respectively.

The endpoint of Group V is a distinct from that of Groups I/III and IV since monitoring is distinct from treating and inhibiting clot formation, respectively. Group V is distinct from Group II since the resolution steps of each group are different. Therefore, Groups I-V are patentably distinct each from the other.

3. Because Inventions I-V are distinct for the reasons given above, and they have acquired a separate status in the art because the searches of the non patent literature are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

4. If Group I-III or V is elected, the applicant is further required under 35 U.S.C. 121: to elect a **specific Factor IXa compound** such as one recited in claim 4 or claim 27,

5. If Group I or V is elected, the applicant is further required to elect a **specific**

ischemic disorder such as one recited in claim 7,

6. If Group II or V is elected, the applicant is further required to elect a **specific means of measuring stroke outcome** such as one recited in claim 24 or claim 32, respectively.

7. If Group I is elected, the applicant is further required:
A) to elect a **specific indirect fibrinolytic agent**, such as one recited in claim 20,
B) to elect a **specific direct fibrinolytic agent**, such as one recited in claim 19,
C) to elect a **specific surgery**, such as one recited in claim 9,
I) if organ transplantation surgery is elected then applicant is further required to elect a **specific organ surgery**, such as one recited in claim 10,
D) to elect a **specific period of time**, such as one recited in claims 11-14.

8. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. The following claim(s) are generic: claims 1-28 and 31-32.

12. The species are distinct each from the other for the following reasons:

A) The recited Factor IXa compounds, indirect fibrinolytic agents, and direct fibrinolytic agents each have distinct biophysical properties and structures and therefore a disclosure showing treating, identifying or assaying with one compound,

one indirect fibrinolytic agent, and one direct fibrinolytic agent would not teach or necessarily suggest treating, identifying or assaying with another recited compound, indirect fibrinolytic agent, or direct fibrinolytic agent , respectively.

B) The recited surgery, and the recited organ surgery each have distinct process steps and procedures.

C) The recited means of measuring stroke outcome each have distinct process steps and procedures.

D) The recited ischemic disorders each have distinct symptoms and etiologies.

E) The recited period of times of administration each have distinct process and method steps with conceivably distinct outcomes

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to

responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
August 27, 2001

David A Saunders

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